# **EFSA and GMOs**

Susan Bardocz and Arpad Pusztai

# HISTORY

## EFSA – how it come to be

Food scares in 80s, 90s

- Salmonella in eggs
- Listeria histeria
- Verotoxic E.Coli in old people's home
- BSE
- Dioxin in poultry feed
- Feeding human suede to pigs in
- Blueprint: 2000 FSA in Britain
- GMO
- 2002 EFSA is "made"
- 2002- FSAs in all EU countries

EFSA is an agency of the European Union that provides independent scientific advice and communication on existing and emerging risks associated with the food chain. The Authority's work covers all matters with a direct or indirect impact on food and feed safety, including animal health and welfare, plant protection and plant health and nutrition. **EFSA supports the European Commission, European Parliament and EU** member states in taking effective and timely risk management decisions that ensure the protection of the health of the European consumers and the safety of the food and feed chain.

### EFSA

- Authorised by the EU Parlament
- Executive Director: elected for 5 years executive
- Management Board: Strategic and financial responsibility
- All other employees are selected by EFSA Board and members

The Executive Director is assisted by an Advisory Forum composed of representatives of national bodies responsible for risk assessment in the Member States, with observers from Norway, Iceland, Switzerland and the European Commission.

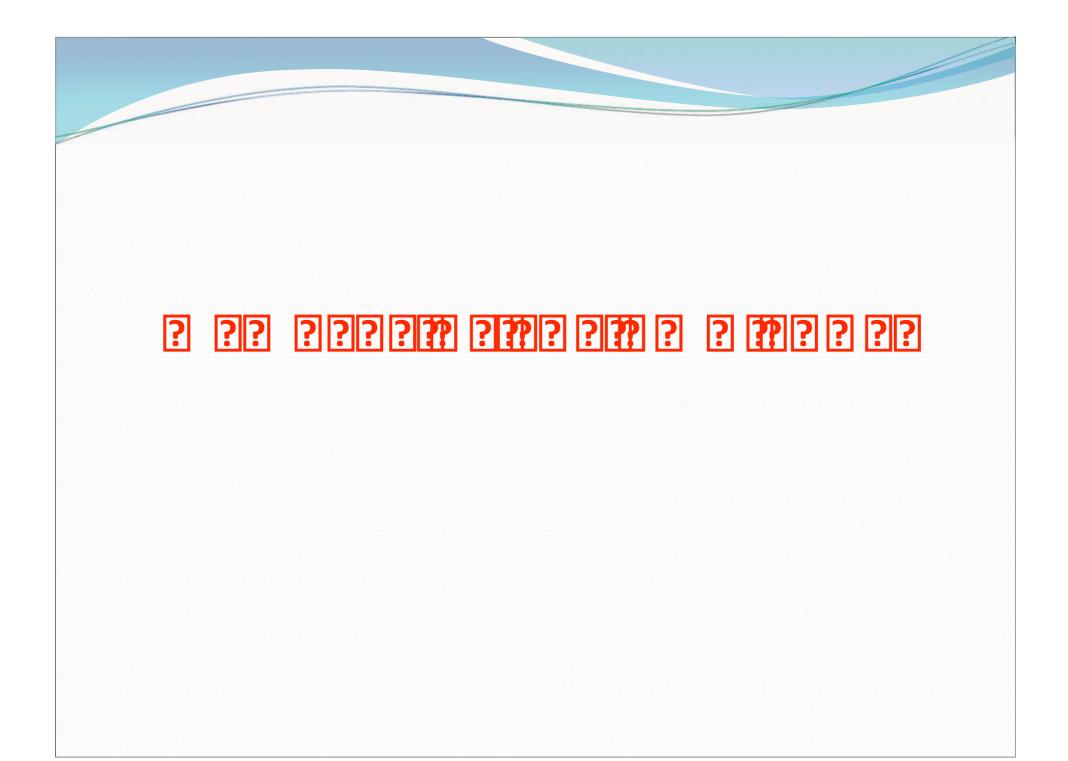
EFSA's scientific opinions and advice are provided by the Scientific Committee (SC) and Scientific Panels, each within their own sphere of competence. EFSA's Scientific Committee and Panels are composed of highly qualified experts in scientific risk assessment.

# SELECTION OF CANDIDATES

- Science degree
- Research experience and degree
- Language skills
- Short list for Interview
- Asked about their opinion of GMOs
- Depending on their view they will get or not the job

# **THE GMO PANEL**

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#### **KUIPER, Harry - CHAIR**

EFSA involvement: Member - GMO Panel 2009-2012, Member - Scientific Committee 2009-2012 (SC), Chair -90-day feeding trials of whole food/feed (SC), Member -Applications-Food and Feed (GMO), Member -Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Member – Guidance on human health risk assessment of GM animals (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO), Member - Strategies for Statistical Analysis of Data Generated for the Comparative Food Safety Evaluation of GMOs (GMO)

#### Joe N. Perry, Vice-Chair

**EFSA involvement:** Member - GMO Panel 2009-2012 (GMO), Member - Applications-Environment (GMO), Member - Guidance on human health risk assessment of GM animals (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO), Member - Self task on non-target organisms (GMO), Member - Strategies for Statistical Analysis of Data Generated for the Comparative Food Safety Evaluation of GMOs (GMO), Member - Sub Working Group Environment ERA GD (GMO), Chair - Sub group Statistics ERA Guidance (GMO), Member - WG on Handling Left Censored Data (Data Collection Exposure)

Employment 08/1976 - 06/2006 -Rothamsted Research Station: Research into GMOs, publishing papers on GMO related topics Please note that although my employment at Rothamsted went from 1976 to 2006, it ended just one month prior to me starting as an EFSA expert on the GMO Panel

#### Sirpa Kärenlampi, Vice-Chair

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member -Applications-Molecular Characterisation (GMO), Member - Genetically Modified Microorganisms (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Vice-Chair - Updated GMM GD WG (GMO) 2003 – 2006 EFSA GMO Panel, public. Scientific opinions in the area of genetically modified plants.

**1997 - 2003: Scientific Committee on Plants, European Commission. Scientific opinions in the area of genetically modified plants.** 

Teaching: plant biochemistry, plant genetic engineering, GMO legislation, plant issue culture. Research: several Ph.D. students are working on GMOs. A number of scientific publications related to GMOs and profiling techniques.

#### Hans Christer Andersson

**EFSA involvement: Member - GMO Panel 2009-2012** (GMO), Member - Applications-Food and Feed (GMO), Member - Assessment of Allergenicity of GM foods (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or nonfeed purposes (GMO), Member - Guidance on human health risk assessment of GM animals (GMO), Member - Strategies for Statistical Analysis of Data Generated for the Comparative Food Safety Evaluation of GMOs (GMO) **Senior Toxicologist** 

#### **Salvatore Arpaia**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member -Applications-Environment (GMO), Member - Self task on non-target organisms (GMO), Member - Strategies for Statistical Analysis of Data Generated for the Comparative Food Safety Evaluation of GMOs (GMO), Member - Sub group Statistics ERA Guidance (GMO) Researcher, Member of a Scientific Advisory Body.

Preparation of an operational model applied to the evaluation of environmental risks dylue to the cultivation of GMOs

2002 - ENEA - Italian National Agency for New Technology, Energy and the Environment. Public Research Institute. Research on GMOs, publishing papers on GMO-related topics, insect ecology and biodiversity and risk assessment.

ENEA is not involved in the evaluation of application dossiers with the Italian Competent Authorities.

#### **Detlef Bartsch**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Environment (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Member - Self task on non-target organisms (GMO), Member - Sub Working Group Environment ERA GD (GMO), Member - Sub group Statistics ERA Guidance (GMO)

2002 – now: Federal Ministry for Education and Research (BMBF), Federal Ministry for Food, Consumer Protection and Agriculture, Berlin, public My task is to evaluate basic research projects in the field of GMO Biosafety.

#### **Josep Casacuberta**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Molecular Characterisation (GMO), Member - Guidance on human health risk assessment of GM animals (GMO), EFSA, public. Ad hoc Expert for the GMO Panel

**IBMB-CSIC**, a public research Institute of the CSIC with research groups working on different aspects of animal and plant molecular biology.

#### **Howard Davies**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member -Applications-Molecular Characterisation (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO)

2005 – : **Dundee Science Centre**, **Dundee Scotland**, UK, private Member of Board of Directors. It is only concerned in a very limited way with GMOs and only for general transfer of knowledge to and debate with the public.

2009 - now: Fondazione Edmund, Mach, Istituto Agrario di San Michele, Trento, Italy, public. Science advisory board member of crop research centre funded primarily by Trento region.

2004 - now: Defra Hortlink Programme Grant Review Panel, London, UK. Public. Advise on suitability of grant submssions for

industry/Government LINK grants

#### **Gerhard Flachowsky**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - 90-day feeding trials of whole food/feed (SC), Member - Applications-Food and Feed (GMO), Member -Guidance on human health risk assessment of GM animals (GMO)

2008 - : Institut für Tierernährung, Friedrich-Loeffler-Institut (FLI), Bundesforschungsinstitut für Tiergesundheit, Braunschweig, Germany, under the Federal Ministry for Food, Agriculture and consumer Protection, with a consultative function which helps provide the scientific basis for political decision making.

### Patrick du Jardin

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Molecular Characterisation (GMO), Member - Guidance on human health risk assessment of GM animals (GMO)

2007: Ad hoc expert of the Scientific committee on Transgenic plants (for the Section of Biosafety and Biotechnology of the Scientific Institute of Public Health Louis Pasteur), Brussels, public. Technical advice on specific matters

#### **Huw Jones**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Molecular Characterisation (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO)

1993 - : British Biotechnology PLC / Vernalis plc,
Cambridge UK, private. Approx 20 shares in Vernalis
(previously British Biotechnology) a pharmaceutical company.

#### **Jozsef Kiss**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Environment (GMO), Member - Self task on non-target organisms (GMO), Hearing Expert - Sub Working Group Environment ERA GD (GMO)

Integrated Pest Management, Biological control, Effect on transgenic crops. 2007 – now: EU-6 ENDURE Network of Excellence (European Network for the Durable Exploitation of Crop Protection Strategies)

#### **Gijs A. Kleter**

**EFSA involvement: Member - GMO Panel 2009-2012** (GMO), Member - 90-day feeding trials of whole food/feed (SC), Member - Applications-Food and Feed (GMO), Member - Assessment of Allergenicity of GM foods (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Member - Guidance on human health risk assessment of GM animals (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO), Member - Strategies for Statistical **Analysis of Data Generated for the Comparative Food Safety Evaluation of GMOs (GMO)** 

#### **Antoine Messéan**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Environment (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO), Member - Sub Working Group Environment ERA GD (GMO), Member - Sub group Statistics ERA Guidance (GMO)

#### Kaare Magne Nielsen

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Molecular Characterisation (GMO), Member - Genetically Modified Microorganisms (GMO)

EU Cost Action network on "Arthropod Symbioses: from fundamental studies to pest and disease management"

#### **Annette Poeting**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Food and Feed (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or nonfeed purposes (GMO), Member - Novel Foods (NDA), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO)

#### **SWEET**, Jeremy

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Environment (GMO), Member - Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Chair - Guidance on environmental risk assessment of GM fishes (GMO), Member - Self task on non-target organisms (GMO), Member - Sub Working Group Environment ERA GD (GMO), Member - Sub group Statistics ERA Guidance (GMO)

2007 - now: **GSK ( GlaxoSmithKline)** -Commercial company, private shares – 120 at this date.

2000 - now: BP –Commercial company, private. 97 Shares.

2000 - now: Cornwall Farmers -Commercial company. Private. 100 shares.

(Close family member) 2000 - now: Arla Foods. Private company, 100 Shares. (Close family member)

2000 - now: Northern Foods. Private company, UK. Private.199 shares.

### Christoph Tebbe

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Applications-Environment (GMO), Member - Genetically Modified Microorganisms (GMO), Member- Updated GMM GD WG (GMO)

#### **Atte Johannes von Wright**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member - Amino Acids (FEEDAP), Member - Applications-Food and Feed (GMO), Member – Biomasses (FEEDAP), Member - ESCO WG on Non-Plastic FCM (CEF), Member -Maintanance of the list of QPS microorganisms intentionally added to food or feed (2009 update) EFSA-Q-2009-00459 (BIOHAZ), Member - Micro-organisms (FEEDAP), Member -**Organic Acids (FEEDAP), Member - Updated GMM GD WG** (GMO), Member - Wg on QPS 2010 update (EFSA-Q-2010-**00086) (BIOHAZ)** 

2006 - now -Name: BioSafe Special Laboratory Services Ltd, Kuopio, Finland, private.

#### **Jean-Michel Wal**

EFSA involvement: Member - GMO Panel 2009-2012 (GMO), Member -Applications-Food and Feed (GMO), Member - Assessment of Allergenicity of GM foods (GMO), Member - Food Allergy (NDA), Member - Guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (GMO), Member - Self Task on Selection of comparators for the risk assessment of GM plants (GMO)

**2002** - Organisation for Economic Co-operation and Development (OECD), Paris, France, public, ad hoc expert in the Task Force for the Safety of Novel Foods and Feeds

2002 – now: FAO-Codex alimentarius, Rome, Italy, public, ad hoc expert in working groups involved in develoment/updating of guidelines for food/feed safety risk assessment of foods derived from biotechnology.

2006 - 2007: European Parliament, public. External expert on food safety for the field of GMOs to advise the Committee on Environment, Public Health and Food Safety of the European Parliament.

# WHO ARE THEY?

- Are the same people controlling of all aspects of GMOs?
- Influence research founding?
- Influence political decisions?
- A revolving door approach from industry to EFSA, from EFSA to industry?
- Are they ignorant?
- Are they uncertain?
- Do they know the risks?

### Do you trust the MAKER?

# WOULD YOU TRUST THE RISK ASSESSORS?

Updated guidance Document for the risk assessment of genetically modified plants and derived food and feed

- First draft 176 pages (update) written by the EFSA GMO Panel in 2008
- Revision selected comments are taken only, mostly deletions
- Version B sent out the 2 days before meeting, document re-edited and re-styled
- After the meeting chance to send in observations,
- Several corrections are ignored
- Version C (Final?) ONLY 68 pages, 2010



#### 944 7.1. Comparative analysis

945 The comparative analysis of composition and agronomic and phenotypic 946 characteristics:

947 • represents, together with the molecular characterisation, the starting point
948 to structure and conduct the risk assessment of a new GM plant and its
949 derived products;

950 • identifies similarities and differences in composition, agronomic
951 performance and phenotypic characteristics (intended and unintended
952 alterations) between the GM plant and its most appropriate non-GM
953 comparator which has a history of safe use;

954 • identifies similarities and differences in composition between derived 955 food/feed product(s) and their comparator;

#### **1.3. Comparative analysis**

The comparative analysis of composition and agronomic as well as phenotypic characteristics shall constitute, together with the molecular characterisation, the starting point to structure and conduct the risk assessment of a new GM food and feed and its derived products. It shall aim at:

•identifying similarities and differences in composition, agronomic performance and phenotypic characteristics (intended and unintended alterations) between the GM plant and its conventional counterpart;

•identifying similarities and differences in composition between the GM food and feed and its counterpart.

•SO< WE ARE BACK TO SUBSTANCIAL EQUVIVALENCE!!!

Where no appropriate conventinal counterpart can be identified, a comparative safety assessment cannot be made and consequently a safety and nutritional assessment of the GM food and feed shall be carried out as for other novel foods that do not have conventional counterparts (e.g. where the GM food and feed is not closely related to a food and feed with a history of safe use or where a specific trait or specific traits are introduced with the intention of bringing complex changes in the composition of the GM food and feed.

The appropriate conventional counterpart for stacked events shall be selected in accordance with the principles defined previously in the present section. In addition, single parental GM lines or GM lines containing previously stacked events that have been fully risk assessed may also be included as additional comparators. The applicant shall provide detailed information justifying the choice of additional comparators.

### **EFSA EMPLOYEES ARE**

### > NON-ELECTED

### >HOLD NO LEGAL RESPOSIBILITY FOR THEIR DECISIONS!!!

# WHAT ARE WE GOING TO DO NEXT?